Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2000 list were published in the Federal Register in May 2000.

Supplemental Approvals

ANADA Number: 200-221

This supplemental application provides for subcutaneous use of a cattle ear implant for pasture cattle for increased rate of weight gain. Technical changes are also made.

Trade Name:	Component® TE-G
Ingredients:	Trenbolone acetate, estradiol
Sponsor:	Ivy Laboratories, Division of Ivy Animal Health, Inc.
Approval Date:	March 6, 2000
Status:	Over-the-counter
Route:	Subcutaneous
Species:	Cattle
Drug Form:	Implant
Concentration:	40 mg trenbolone acetate, 8 mg estradiol
Indications:	For increased rate of weight gain in pasture cattle (slaughter, stocker, and feeder steers and heifers).
Tolerance:	21CFR 556.240: Estradiol: Residues for estradiol and related esters may not exceed the following increments above the concentrations of estradiol naturally present in the untreated animals; in the uncooked edible tissues of heifers, steers, and calves: 120 parts per trillion (ppt) for muscle, 480 ppt in fat, 360 ppt for kidney, and 240 ppt for liver. 21CFR 556.739: Trenbolone: A tolerance for total trenbolone residues in uncooked edible tissues of cattle is not needed. The ADI of 0.0004 milligram per kilogram of body weight per day has been established.
Withdrawal:	Zero days

21CFR 522.2477

Change of Sponsor Name and Address

From: Global Pharmaceutical Corp.
Castor and Kensington Aves.
Philadelphia, PA 19124
Labeler code: 000115

To: IMPAX Laboratories, Inc.
30831 Huntwood Ave.
Hayward, CA 94544

Suitability Petition Action

Number:	00P-0596/CP1
Sponsor:	Phoenix Scientific, Inc.
Petition:	Request permission to file an ANADA for a generic new animal drug, phenylbutazone, which differs from the pioneer product, phenylbutazone (Phoenix Scientific, Inc.), NADA 091-818, by the following characteristic: The generic product will consist of a different physical form, powder, whereas the pioneer approved product is a tablet.
Action:	Not required (denied on) May 5, 2000.